


EXHIBIT 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069		DATE(S) OF INSPECTION 01/10/2006 - 02/08/2006* FBI NUMBER 2244683	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Divya C. Patel, President			
FIRM NAME Amide Pharmaceutical, Inc		STREET ADDRESS 101 East Main St	
CITY, STATE, ZIP CODE, COUNTRY Little Falls, NJ 07424-5608		TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
The following observations relate to coverage of the Postmarketing Adverse Drug Experience Reporting System:			
OBSERVATION 1			
Adverse drug experience information has not been reported to FDA.			
Specifically, the following adverse drug experiences or information regarding serious, unexpected adverse drug experiences were not submitted to FDA.			
(a) Unsubmitted serious, unexpected 15-day alert experiences, where Amide (the application holder or responsible party) did not submit to FDA, e.g.:			
MRN	Date Rcvd by Mfr	Suspect Amide Drug	Adverse Experiences
00-002	12/17/1999	Phentermine	Primary pulmonary hypertension, Valvular heart disease (regurgitation), Neurotoxic injuries (NOS) (neurotoxicological disorder)
02-006	5/3/2002	Digitek (digoxin) Tablets	Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight Decreased
03-017	3/28/2003	Digitek (digoxin) Tablets 0.25mg	Generalized weakness, Atrial fibrillation, Feeling of semi-consciousness, Possible digoxin toxicity
04-043	7/23/2004	Phenazopyridine HCl Tablets 200mg	Asthenia, Feeling abnormal, Headache, Chest discomfort, Nausea, Feeling jittery, Oedema peripheral, Hypersensitivity, Rash
05-005	1/21/2005	Phentermine HCl Tablets 37.5mg	Panic attack, Anxiety, Chemical imbalance, Comatose for six months, Lost memory
05-087	10/5/2005	Phentermine	Death from cardiac dysrhythmia, Overdose
RELEASE			
SEE REVERSE OF THIS PAGE			REVIEWED BY <u>SAD</u> C.O. <u>5/22/07</u> DATE
		DATE ISSUED 02/08/2006	
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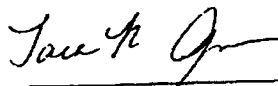
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(b) Unreported or inaccurate information from serious, unexpected 15-day alert reports, as documented on telephone records or in forwarded case information from a contracted affiliate, e.g.:


MRN	Date Rcvd by Mfr	Suspect Amide Drug	Adverse Events
00-015	5/9/2000	Digitex Tablets (digoxin) 0.25mg / ANDA 40-282	Death in 2.5 hours after ingestion of first tablet
• Unreported Information: Previous Condition - Diabetic			
01-020	9/7/2001	Digitex (digoxin) 0.125g Tablets / ANDA 40-282	Feet swelling
• Unreported Information: Event reappeared after reintroduction of medication, dehydration, low potassium level, arrhythmia			
05-085	9/29/2005	Dexchlorpheniramine Maleate Tablets ER 6mg / Prescription without an approved application	Dizziness, Hallucination, Fall resulting in 3 broken toes and bruised ribs, Overdose, Lack of effect
• Unreported Information: Incorrect concomitant medication reported instead of [redacted] Additional suspect medications were identified by the reporter but not listed as suspect medications on the Med Watch Form 3500A, Provided dosages of concomitant medications were not listed, Narrative incorrect in that broken ribs were listed although broken toes were reported, Narrative was summarized and not complete			


(c) Unreported follow-up information from the patient's doctor regarding the following serious, unexpected adverse drug experience:


MRN	Initial Date Rcvd by Mfr	Follow-up Information Date Rcvd by Mfr	Suspect Amide Drug	Adverse Events	Follow-up Information reported by Physician
00-015	5/9/2000	7/24/2000	Digitex Tablets (digoxin) 0.25mg	Death in 2.5 hours after ingestion of first tablet	Allergic to codeine, Cause of Death: Arrest


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<p>OBSERVATION 2</p> <p>Adverse drug experiences that were the subject of post marketing 15-day reports were not investigated.</p> <p>Specifically, there were no follow-up investigations for the following serious, unexpected experiences:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: center;">MRN</th> <th style="text-align: center;">Date Rcvd by Mfr</th> <th style="text-align: center;">Suspect Amide Drug</th> <th style="text-align: center;">Adverse Experiences</th> <th style="text-align: center;">Submitted to FDA</th> <th style="text-align: center;">Expected Follow-up</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">01-020</td> <td style="text-align: center;">9/7/2001</td> <td>Digitek (digoxin) Tablets 0.125mg</td> <td style="text-align: center;">Swollen feet</td> <td style="text-align: center;">Yes</td> <td>Determine resolution of experience, as patient's experience had not resolved at the time of reporting.</td> </tr> <tr> <td style="text-align: center;">02-006</td> <td style="text-align: center;">5/3/2002</td> <td>Digitek (digoxin) Tablets</td> <td>Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight decreased</td> <td style="text-align: center;">No</td> <td>Determine resolution of experiences, as patient's experiences had not resolved at the time of reporting.</td> </tr> <tr> <td style="text-align: center;">05-087</td> <td style="text-align: center;">10/5/2005</td> <td>Phentermine</td> <td>Death from cardiac dysrhythmia, Overdose</td> <td style="text-align: center;">No</td> <td>Determine patient history, concomitant medications, laboratory tests, indication for use</td> </tr> </tbody> </table>						MRN	Date Rcvd by Mfr	Suspect Amide Drug	Adverse Experiences	Submitted to FDA	Expected Follow-up	01-020	9/7/2001	Digitek (digoxin) Tablets 0.125mg	Swollen feet	Yes	Determine resolution of experience, as patient's experience had not resolved at the time of reporting.	02-006	5/3/2002	Digitek (digoxin) Tablets	Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight decreased	No	Determine resolution of experiences, as patient's experiences had not resolved at the time of reporting.	05-087	10/5/2005	Phentermine	Death from cardiac dysrhythmia, Overdose	No	Determine patient history, concomitant medications, laboratory tests, indication for use
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<p>OBSERVATION 3</p> <p>Adverse drug experience information obtained or otherwise received from any source was not reviewed, including information from commercial marketing experience and reports in the scientific literature.</p> <p>Specifically, incoming adverse drug experiences from spontaneous, clinical trials, and scientific literature are often not reviewed for seriousness and/or expectedness. Any adverse experience which the firm submits to FDA is submitted as a 15-day expedited report.</p> <p>Additionally, the firm receives published literature on a monthly basis for review, but does not capture serious, unexpected experiences for cases requiring 15-day expedited reports, per Departmental Operating Instructions RA-009, Adverse Drug Experiences (ADE) Reporting to FDA, effective 7/20/2002.</p>																													
<p>OBSERVATION 4</p> <p>Individual ADEs which were not reported to FDA in a post marketing 15-day alert have not been included in a periodic safety report.</p> <p>Specifically, the firm has never filed a periodic report with FDA. ANDA and NDA approval dates range from 2/28/1997 to</p>																													
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<p>10/24/2005. The firm's procedure, Departmental Operating Instructions RA-009, Adverse Drug Experiences (ADE) Reporting to FDA, effective 7/20/2002, requires the submission of periodic reports. Several adverse experiences remained unreported, e.g.:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 10%;">MRN</th> <th style="width: 10%;">Date Rcvd by Mfr</th> <th style="width: 25%;">Suspect Amide Drug / ANDA</th> <th style="width: 35%;">Adverse Events</th> <th style="width: 20%;">Seriousness / Expectedness</th> </tr> </thead> <tbody> <tr> <td>03-011</td> <td>3/17/2003</td> <td>Digitek (digoxin) Tablets 0.125mg / ANDA 40-282</td> <td>Unresolved loss of taste</td> <td>Non-serious / Unexpected</td> </tr> <tr> <td>03-035</td> <td>10/21/2003</td> <td>Betaxolol Tablets 10mg / ANDA 75-541</td> <td>Tremors, Severe nervousness</td> <td>Non-serious / Expected</td> </tr> <tr> <td>04-002</td> <td>1/23/2004</td> <td>Digitek (digoxin) Tablets 0.125mg / ANDA 40-282</td> <td>Frequent bowel movements, Fatigue, Lightheadedness, Paleness, Abnormal feeling</td> <td>Non-serious / Unexpected</td> </tr> <tr> <td>04-038</td> <td>8/6/2004</td> <td>Digitek (digoxin) Tablets 0.25mg / ANDA 40-282</td> <td>Appetite decreased, Weight loss, Tiredness, Tremors</td> <td>Non-serious / Unexpected</td> </tr> <tr> <td>04-039</td> <td>8/10/2004</td> <td>Phentermine HCl Tablets 37.5mg / ANDA 40-190</td> <td>Drug didn't show up in blood test, Insomnia</td> <td>Non-serious / Unexpected</td> </tr> <tr> <td>04-042</td> <td>8/18/2004</td> <td>Digitek (digoxin) Tablets 0.25mg / ANDA 40-282</td> <td>Black tooth deposits</td> <td>Non-serious / Unexpected</td> </tr> <tr> <td>04-053</td> <td>9/20/2004</td> <td>Digitek (digoxin) Tablets 0.125mg / ANDA 40-282</td> <td>Nausea, Vomiting, Confusion, Heart block</td> <td>Non-serious / Expected</td> </tr> <tr> <td>05-045</td> <td>5/2/2005</td> <td>Mirtazapine Tablets 30mg / ANDA 76-241</td> <td>Chest pain, Increased blood pressure, Lack of effect</td> <td>Non-serious / Unexpected</td> </tr> <tr> <td>05-096</td> <td>11/18/2005</td> <td>Quinapril Tablets / ANDA 76-459</td> <td>Unresolved dry cough</td> <td>Non-serious / Expected</td> </tr> </tbody> </table> <p>Further, 17 periodic adverse experiences reported by one nurse in September 2000 were not submitted for atrial fibrillation and lack of effect when taking Digitek (digoxin) Tablets. The nurse reported that 20 patients were switched to the innovator brand and his/her adverse experiences resolved within three weeks; only 3 reports were submitted.</p>					MRN	Date Rcvd by Mfr	Suspect Amide Drug / ANDA	Adverse Events	Seriousness / Expectedness	03-011	3/17/2003	Digitek (digoxin) Tablets 0.125mg / ANDA 40-282	Unresolved loss of taste	Non-serious / Unexpected	03-035	10/21/2003	Betaxolol Tablets 10mg / ANDA 75-541	Tremors, Severe nervousness	Non-serious / Expected	04-002	1/23/2004	Digitek (digoxin) Tablets 0.125mg / ANDA 40-282	Frequent bowel movements, Fatigue, Lightheadedness, Paleness, Abnormal feeling	Non-serious / Unexpected	04-038	8/6/2004	Digitek (digoxin) Tablets 0.25mg / ANDA 40-282	Appetite decreased, Weight loss, Tiredness, Tremors	Non-serious / Unexpected	04-039	8/10/2004	Phentermine HCl Tablets 37.5mg / ANDA 40-190	Drug didn't show up in blood test, Insomnia	Non-serious / Unexpected	04-042	8/18/2004	Digitek (digoxin) Tablets 0.25mg / ANDA 40-282	Black tooth deposits	Non-serious / Unexpected	04-053	9/20/2004	Digitek (digoxin) Tablets 0.125mg / ANDA 40-282	Nausea, Vomiting, Confusion, Heart block	Non-serious / Expected	05-045	5/2/2005	Mirtazapine Tablets 30mg / ANDA 76-241	Chest pain, Increased blood pressure, Lack of effect	Non-serious / Unexpected	05-096	11/18/2005	Quinapril Tablets / ANDA 76-459	Unresolved dry cough	Non-serious / Expected
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<p>OBSERVATION 5</p> <p>Written procedures have not been developed for the evaluation and reporting to FDA of post marketing adverse drug experiences.</p> <p>Specifically:</p> <p>(a) There is no procedure regarding the initiation of follow-up investigations for serious, unexpected adverse experiences.</p>																																																						
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<p>(b) There is no procedure to adequately complete the MedWatch Form 3500A in that the firm never completes Adverse Event Terms, Section G8.</p> <p>(c) There is no procedure for the maintenance of records to assure timely submission of 15-day alert reports to FDA.</p> <p>(d) There is no procedure for a review of MedWatch Forms to assure the accuracy of information reported to FDA. The firm does not conduct reviews of the cases prior to submission, e.g. information in the 'Describe event or problem', Section B5, was often incomplete and 'Date received by manufacturer', Section G4, was often inaccurate.</p>	
The following observations relate to coverage of Good Manufacturing Practices:	
Quality System	
OBSERVATION 6	
There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been thoroughly distributed.	
Specifically:	
<p>(a) The firm failed to investigate thirteen consumer complaints for Amidrine Capsule breakages, nine received 2/27/2004 - 7/16/2004 and four received 2/9/2005 - 5/17/2005. Four total complaints were received for lot 3636A1 (2/27/2004, 6/15/2004, 6/29/2004, 5/17/2005). No evaluation of the decision and impact on previous batches was conducted regarding a change from red opaque/white opaque capsule shells to white opaque/white opaque capsule shells. The capsule shells were changed upon advice from the capsule shell manufacturer to prevent breakage.</p> <p>Further, although a change control request was approved on 7/27/2004 approving the use of white opaque/white opaque capsules, the firm continued to use the red opaque/white opaque capsules in three additional batches (7/29/2004, batch 4360A; 8/6/2004, batch 4397A; 8/9/2004, 4398A) until the supply was exhausted.</p> <p>(b) The firm failed to thoroughly investigate an intact metal screw found in a bottle of Vitaplex Tablets, lot 4747A1, as reported in Consumer Complaint 04-067, dated 12/5/2004. Although the complaint investigation determined that the screw was from an Amide packaging machine, no additional investigation was conducted.</p> <p>(c) The firm failed to investigate an out-of-specification percent yield for bulk Amidrine Capsules, lot 5996A (94.46%; spec. 94.46%), on 12/27/2005.</p>	
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OBSERVATION 7	
<p>Complaint procedures are deficient in that they do not include provisions that allow for the review and determination of an investigation by the quality control unit.</p> <p>Specifically, the firm's complaint handling procedure does not cover the initiation of a formal investigation when necessary, such as multiple complaints for the same lot of product or confirmed contamination complaints. For example, investigations were not conducted when four complaints were received for cracked Amidrine Capsules, lot 3636A1, or for an intact metal screw, confirmed to be from the firm's packaging equipment, found in a bottle of Vitaplex Tablets.</p>	
OBSERVATION 8	
<p>Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.</p> <p>Specifically, the qualification and start-up procedures are inadequate for the [REDACTED] in that the equipment was not challenged prior to the inspection to assure accuracy, per the equipment manual. The [REDACTED] is a 100% capsule weight sorter used to separate low and high weight Amidrine Capsules and was qualified on 12/1/2005. Challenge tests conducted during the inspection failed to reject all out-of-specification capsules.</p> <p>Regarding the manual encapsulation process, the in-process testing was not evaluated after implementation of the [REDACTED] resulted in additional rejects. The in-process testing involves weighing [REDACTED] individual capsules every [REDACTED] and one group of [REDACTED] capsules every [REDACTED]. The [REDACTED] rejects have accounted for approximately 1-3% of overall product yield for each of the nine lots which used the [REDACTED], an out-of-specification product yield for Batch 5996A was observed (94.46%, approximately 3% rejected by the [REDACTED] spec [REDACTED]). The firm has not evaluated the adequacy of the in-process testing, which potentially impacts the capsules released not using the [REDACTED] and the adequacy of the manual encapsulation manufacturing process.</p>	
<p>* DATES OF INSPECTION: 01/10/2006(Tue), 01/11/2006(Wed), 01/12/2006(Thu), 01/23/2006(Mon), 01/24/2006(Tue), 01/25/2006(Wed), 02/06/2006(Mon), 02/08/2006(Wed)</p>	
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FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:			
			
Tara R. Gooen, Investigator			
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